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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FORTUNA, ANA M	

ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
07/09/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Office Action Summary	Application No.	Applicant(s)	
	10/748,962	KOPF ET AL.	
	Examiner	Art Unit	
	Ana M. Fortuna	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *29-38 and 40-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/8/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-28, and 39, drawn to a membrane system, classified in class 210, subclass 257.2.

   II. Claims 29-38, drawn to a process of fractionating milk, classified in class 426, subclass 491.

   II. Claims 40-43, drawn to milk compositions, classified in class 426, subclass 657.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process can be practiced with a distinct apparatus, e.g. chromatography, cross-flow chromatography, precipitation, and includes separation of specified compounds that do to limit the apparatus of group I, e.g. hormones, monoclonal antibodies, etc.

3. Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process

(MPEP § 806.05(f)). In the instant case the product can be made by a distinct process, such as depth filtration and chromatography.

4. Inventions I and II are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a materially different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the apparatus of group I is connected to a milk source for fractionating milk components, e.g. protein, casein, etc, however, is connected to any structure making the products of group III.

5. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. During a telephone conversation with Marianne Fiuerer on 7/01/08 a provisional election was made with traverse to prosecute the invention of group I, claims 1-28 and 39. Affirmation of this election must be made by applicant in replying to this Office action. Claims 29-38 and 40-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

7. Claims 1-28 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is directed to system having a source of milk, and "one" or multiple "cross-flow filtration modules", and conduits. The term cross-flow filtration modules" is incomplete, as to whether the modules are "membrane modules". Claim 1 also lack structure regarding to how are the modules arranged it he system with respect to the permeate and retentate leaving each of the modules. Claim 7 is incomplete as to what fraction contains the casein and what fraction contains the casein depleted stream. Claims 13, 14-16 are redundant regarding to the casein separation module; it is unclear whether the filtration modules in claim 1 are capable of separating the casein, or whether and additional filter is provided for the purpose, and the subsequent third, fourth, etc. refer back to the multiple cross-flow filters of claim 1, or they are additionally provided. Claims 17-18 are indefinite, the claim does not provide and apparatus structure that clearly indicates the sequence of treatments in the

system, e.g. how the permeate and/or retentate conduits are arranged with respect to second, third , etc. membrane modules in the system. Claim 23 is unclear and redundant. The claim should be directed to the alternative of providing the bacteria removal filter before the at east one module; the alternative excluding this filer corresponds to the embodiment of claim 1, and the additional filters should refer back to the "said at least one or more modules. In claim 39, step (b) the conduit is not an optional element because is part of the (membrane) module, e.g. for removing the products resulting from the separation; the claim is also indefinite as to what fraction is the permeate or the retentate in each separation stages.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Ehsani et al (US 6,426,109). As to claims 1-3, patent 109 discloses a process of treating a milk source, e .g skin milk or colostrum by a cross-flow microfiltration membrane, the system is not illustrated but includes at least one microfiltration membrane made of a polymeric material. The inlet (feed inlet to the membrane or microfilter) and outlets (e.g. for permeate and retentate) and an inherent part of the membrane unit (abstract, column 2, lines 41-52; column 3, lines 38-68). Regarding claim 4, defattening the collostrum is

required in patent '109; the use of a "cream separator" or centrifuge is disclosed (column 3, lines 11-13). Combining additional membrane steps to concentrate the filtered collostrum to enrich the recovered protein is further disclosed in this patent (column 4, second paragraph).

10. Claims 1-2, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Lidman (US 4,970,989). Lidman discloses and a system includes a source of milk connected through conduits with a cross-flow (ultrafilter membrane), and discharge conduits (elements 1, 10, 5, 6, 7, 11 and 14, sole figure). Producing a casein depleted fraction is disclosed in this patent, e.g. a permeated containing fraction containing water, milk sugar, and low molecular salts (column 1, lines 1-34); the other components of milk, such as casein are inherently retained by the ultrafilter.

11. Claims 1-4, 5, are rejected under 35 U.S.C. 102(b) as being anticipated by Holm, deceased et al (US 4,876,100). Patent '100 teaches a system treating a milk source and comprising a fat separator, and treating skim milk produced by cross-flow microfiltration (abstract, fig. 1, column 2, lines 35-column 3, line 19, and last paragraph bridging column 4; column 6, lines 14-50). As to claims 1-2 the conduits are shown in Fig. 1. As to claims 3-4, the membrane material and cream separators, e.g centrifuge, are disclosed in this patent (column 11, lines 26-41, abstract, and column 6, lines 14-18). Regarding claim 5, pasteurizing, e.g. at a temperature of 77 degree C fro 15 seconds is further suggested in the patent (column 8, lines 9-23).

12. (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent,

except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Lindquist (US 6,737,096). Patent '096 discloses a system including multiple Crossflow membranes connected to a source of milk; the conduits and membrane materials (abstract, Fig. 1, column 2, clines 49-68, column 3, lines 1-25, and column 4, lines 52-63).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ehsani et al (US 6,426,109) .Reference '109 teaches maintaining the milk at a temperature between 2 and 40 degree C, and not allowing the temperature to exceed 40 degree C;

which suggests monitoring the temperature during the process and or installing a conventional temperature sensor to maintain the temperature within the desire range. The skilled in the art at the time this invention was made would have been able to control the temperature in the process by setting a control detecting when the conditions are near to the preset required level, and to adjust the temperature source accordingly.

17. Claims 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidman (US 4,970,989) as applied to claims 1 and 7 above and further in view of Ehsani et al (US 6,426,109). Both of these references are discussed above. Patent '989 fails to disclose the membrane material use in the milk filtration process. Patent '109 teaches using polymeric membranes, e.g cellulose materials for filtering mil to separate bacteria, and further suggest optionally combining microfiltration with ultrafiltration or reverse osmosis membranes depending on the product desired or the nature of the protein to be recovered from the process (column 4, third paragraph). The skilled artisan at the time this invention was made and based on the suggestion of the references above would have been able to use a membrane of the molecular size and material as covered in the present claims. Treating for example a permeate stream from patent '989 by and ultrafiltration membrane is expected to fractionate the dilute permeate stream on additional fractions.

Allowable Subject Matter

18. Claims 13-27, 39 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Drawings

19. The drawings are objected to because in fig. 1, in the second membrane stage, both streams 3 are removed from the same side of the membrane, indicating that both streams are permeate. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Additional references are evidence that filtering milk in "one " crossflow membrane module is conventional in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ana M. Fortuna whose telephone number is (571) 272-1141. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on (571) 272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ana M Fortuna
Primary Examiner
Art Unit 1797

/Ana M Fortuna/

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